

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service Food and Drug Administration

Memorandum

DEC 17 2002

Date: From:

Consumer Safety Officer, Division of Standards and Labeling Regulations, Office

of Nutritional Products, Labeling and Dietary Supplements, HFS-821

Subject:

75-Day Premarket Notification of New Dietary Ingredients

To:

Dockets Management Branch, HFA-305

Subject of the Notification:

Lamila (La Mila)

Firm:

Herbal Powers, Inc.

Date Received by FDA:

March 18, 2002

90-Day Date:

June 16, 2002

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Rhonda R. Kane, M.S., R.D.

Attachments



Food and Drug Administration College Park, MD

MAY 3 | 2002

Annie Eng Herbal Powers, Inc. 2138 West Jackson Suite #2 Chicago, Ilinois 60612

Dear Ms. Eng:

This letter is in response to two separate notifications you submitted to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 350b(a)(2). FDA received and filed the notifications on March 18, 2002. Each notification concerns a different botanical that you assert is a new dietary ingredient. Proposed product names and the Latin binomial names for the ingredients are listed below as stated in your notifications, with the exception that the species names are not capitalized:

- Lamila capsule 270 mg [Labisia pumila F. Vill]
- El Jack capsule 290 mg [Eurycoma longifolia Jack]

Earlier, you submitted notifications for El Jack and Lamila that were dated January 28, 2002, and were received and filed by FDA on February 26, 2002. Mr. Gary Coody on my staff contacted you by phone to request clarification regarding the names for El Jack and Lamila and you responded with the authors' names as indicated above. The author designation, F. Vill, you submitted for the Latin binomial name Labisia pumila is incorrect. The correct Latin binomial name and author designation for this plant is Labisia pumila Benth. & Hook. f. For the purposes of this letter, Labisia pumila will be used to refer to the plant source of Lamila.

Your notification states that Lamila will contain 270 mg per capsule of powdered whole plant of Labisia pumila. The proposed label will instruct consumers to take 2 capsules twice daily one hour before meals. The indicated conditions of use and the proposed text of the label submitted for Lamila include the following statements: may help alleviate fatigue; soothe menopausal symptoms; harmonize female reproductive system and menstrual cycle; enhance women's overall vitality and youthfulness; strengthen uterus; firm breast; enhance overall postpartum recovery; and tighten pelvic muscle after delivery. The proposed label also includes cautionary statements for potential consumers to consult a medical professional if they are taking a prescription medicine, are pregnant or nursing a baby, and to immediately seek the advise of a healthcare professional in case of accidental ingestion or overdosage.

Your other notification states that El Jack will contain 290 mg per capsule of powdered root of Eurycoma Longifolia Jack with label instructions to take 2 capsules daily. The indicated conditions of use for El Jack include the following statements: may help increase the efficiency of the healing system by supporting a healthy immune system; improve overall energy levels; reduce fatigue and exhaustion; enhance overall male

sexual vitality; improve appetite and digestion; and tone skin and muscle. The proposed label also includes cautionary statements for potential consumers to consult a medical professional if they are taking a prescription medicine, are pregnant or nursing a baby, and to immediately seek the advise of a healthcare professional in case of accidental ingestion or overdosage.

The statement "help increase the efficiency of the healing system" may cause El Jack to be represented as a drug. Under 21 U.S.C. 321(g)(1)(B), a drug is defined as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. Therefore, if you intend to make claims of this nature and you want El Jack to be evaluated for its use in the treatment of a disease, you should contact FDA's Center for Drug Evaluation and Research, Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

The law at 21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor submit certain information to FDA at least 75 days before a new dietary ingredient or a dietary supplement containing it is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that the new dietary ingredient or a dietary supplement containing it will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the product's labeling, will reasonably be expected to be safe. If this requirement is not met, the new dietary ingredient or dietary supplement containing it is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B), because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA carefully considered the information in your notifications. We have significant concerns about the basis upon which you concluded that a dietary supplement containing Eurycoma longifolia or Labisia pumila is reasonably expected to be safe when used as recommended or suggested in the products' labeling. These concerns for each ingredient are discussed below.

El Jack

The history of use information provided in your notification states that Eurycoma longifolia is indigenous to Southeast Asia and Indo-China and has been used by the locals in folk medicine as a febrifuge and a remedy for "intermittent fevers." It also refers to Eurycoma longifolia as a "tree of 100 remedies." This history of use information lacks details on the amount, frequency and duration of use for the botanical and whether the plant parts or preparation used are the same as what you intend to market in El Jack. Without these details, it is not possible for FDA to determine how this information relates to your product.

Your notification also includes a photocopy and translation of a registration held by Tomrich Marketing with the Drug Control Authority of Malaysia for "E.L. Jack Capsule"

for the following approved indication: "traditionally used for improving energy, reduce body fatigue and enhance overall performance". You assert in your notification, but without supporting documentation, that over "20 million capsules of E.L. Jack Capsules have been sold in Asia since 1997 and that there have been no serious side effects or drug interactions reported to date when used as directed." FDA is not aware of any systematic collection of data related to adverse effects occurring in individuals using E.L. Jack capsules. Further, absence of adverse event reports does not necessarily mean a particular product or ingredient has not been or is not likely to be associated with an adverse event, nor does it provide adequate evidence of safety for El Jack.

Your notification also includes copies of what appear to be promotional materials and newspaper clippings from unidentified sources intermixed with research publications of invitro and invivo animal studies. Sources are not provided for several of the research publications. Medicinal benefits for Eurycoma longifolia stated in the materials include the following: aphrodisiac, androgenic, antiviral, antimalarial, antipyretic, antihistaminic, antiulcer, antianxiety, anticancer tumor, antihypertensive, antidysentery, and others. None of the papers directly assess safety nor do they provide any safety data for exposure of Eurycoma longifolia in humans. Furthermore, since the relationship between invitro. animal and human exposure is unknown, the applicability of these results to humans is unclear. Of additional concern is the possibility that Eurycoma longifolia may increase testosterone levels, as suggested by the Kwan et. al. paper. If this were confirmed in humans, it could pose a safety risk in men with prostate cancer or other medical conditions. A Certificate of Analysis included in your notification for the Malaysian Eurycoma longifolia capsule drug product indicates that it was assayed for glucocorticosteroids, but not for testosterone or any other androgenic compounds. In summary, your notification has provided no data or publications that can be used to assess the safety of El Jack capsule when used as you direct.

Lamila

Your notification states that Labisia pumila is indigenous to Southeast Asia and has been used by the local women for vitality and restoring youthfulness. This history of use information lacks details on the amount, frequency and duration of use for the botanical and whether the plant parts and preparation used are the same as what you intend to market in Lamila. Without these details, it is not possible for FDA to determine how this information relates to your product.

Your notification also includes a photocopy and translation of a registration held by Tomrich Marketing with the Drug Control Authority of Malaysia for "Labisia pumila capsules" for the following approved indication: "traditionally used for improving energy and women's health." You assert in your notification, but without supporting documentation, that over 2 million capsules of Labisia pumila capsules have been sold in Asia since 1999 and that there have been no serious side effects or drug interactions reported to date when used as directed. FDA is not aware of any systematic collection of data related to adverse effects occurring in individuals using Labisia pumila capsules. Further, absence of adverse event reports does not necessarily mean a particular product or ingredient has not been or is not likely to be associated with an adverse event, nor does it provide adequate evidence of safety for Lamila.

Also attached to your notification are what appear to be promotional materials and other articles from unidentified sources. The materials include statements of medicinal uses for Labisia pumila that include but are not limited to the following: treat dysmenorrhea, rheumatism, gonorrhea, and dysentery; support healthy vaginal flora to prevent irritation and infections; speed up healing of the womb and birth canal after childbirth; strengthen the uterus and bladder from slipping out of place; and alleviate flatulence. The articles state that Labisia pumila contains phytoestrogens. However, the notification contains only one abstract by Jamal et. al. that mentions the presence of weak phytoestrogens in Labisia pumil, but no data is provided. A Certificate of Analysis for the Labisia pumila drug product by Tomrich Marketing indicates that assays were performed for glucocosteroids but not for estrogens or other compounds known to have estrogenic activity. In summary, there is no information in the materials submitted in your notification to assess the safety of Labisia pumila when used as you direct.

Conclusions

For the reasons discussed above, the information in your notification on Lamila does not provide an adequate basis to conclude that it will reasonably be expected to be safe when used under the conditions recommended or suggested in the product's labeling. Also as stated above, because the information in your submission indicates that El Jack is represented as a drug and not a dietary supplement, it would be subject to regulation as a drug. Notwithstanding, even if it could be argued that El Jack is a dietary supplement, the information in your notification does not provide an adequate basis to conclude that it will reasonably be expected to be safe when used under the conditions recommended or suggested in the product's labeling. Therefore, Lamila and El Jack may be adulterated under 21 U.S.C. 342(f)(1)(B) as dietary supplements that contain the new dietary ingredients Labisia pumila or Eurycoma longifolia for which there is inadequate information to provide reasonable assurance that such ingredients do not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notifications will be kept confidential for 90 days after the filing date. After June 16, 2002, the two notifications will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notifications will not be disclosed to the public. Prior to June 16, 2002, you may wish to identify in writing specifically what information you

Page 5 - Ms. Annie Eng

believe is proprietary in each of your notifications for FDA's consideration. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notifications should be redacted before they are posted at Dockets.

Please contact us at (301) 436-2371, if you have questions concerning this matter.

Sincerely yours,

Felicia B. Satchell

Director

Division of Standards

and Labeling Regulations

Office of Nutritional Products, Labeling

Felicia B. Satchell

and Dietary Supplements

Gary Coody FDA 5100 Paintbranch Pkwy HSF 805 College Park, MD 20740-3835

Dear Gary,

I have enclosed 4 copies of new letter for Eyrycoma Longifolia and 4 copies of new letter for Labisia Pumila. These new letters contain the latin author name for each botanical. Please disregard the old letters. Thank you.

Sincerely,

Annie Eng

Herbal Powers Inc.

2138 W. Jackson

Suite # 2

Chicago, IL 60612

H(312)280-1032

C(312)505-1318

RECEIVED 3-18-02 BY: Sinf

FDA Notification of New Dietary Ingredients

Filed By: Herbal Powers

2138 W. Jackson Byld

Suite # 2

Chicago, IL 60612 Tel: (312)280-1032 Cell: (312)505-1318

E-mail: tradereng@hotmail.com

Contract manufacturer: Yanling Natural Hygiene Sdn. Bhd 51200 Kuala Lumpur Malaysia

Distributor in Malaysia: Tomrich Marketing Sdn Bhd 47000 Selangor Malaysia

Dietary Supplement: Lamila Capsule 270MG Labisia Pumila (Author: F. VILL)

Description of Product:

(1) Level of Dietary Ingredients:

270mg per capsule

Pure powder from the whole plant of Labisia Pumila

(2) Conditions of Use: Labisia Pumila may help alleviate fatigue and soothes menopausal

symptoms. Research shows that the phytoestrogents in Labisia Pumila may help enhance women's overall vitally and youthfulness.

Labisia Pumila may strengthen uterus, firm breast and tighten pelvic

muscle after delivery.

(3) History of Use:

Labisia Pumila grows in the rainforest of the Southeast Asia. It has

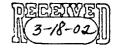
been used by the local women for vitality and restoring

youthfulness. It is known for its beneficial effects for after delivery

care, for harmonize women's reproductive system, and for

establishing a regular menstrual cycle.

Labisia Pumila has been manufactured in capsules form by Tomrich since 1999. Tomrich has sold over 2 million capsules since 1999 in Asia. Labisia Pumila has been certified and approved by the Malaysia Drug Control Authority, National Pharmaceutical Control Bureau, Ministry of Health Malaysia and are manufactured under stringent Good Manufacturing Practices' (GMP) standards. The products are manufactured without adding any additives, preservatives, chemical, artificial flavors or color. No serious side effects or drug interactions have been reported to date when used as directed. For more information on historical use, please refer to the enclosed news



article and research report.

We have enclosed:

- (1) Lab result from National Pharmaceutical Control Bureau (NPCB)
- (ii) Approval certificates by Drug Control Authority, Ministry of Health Malaysia
- (3) Registration Number of Labisia Pumila with Drug Control Authority, ministry of Health Malaysia
- (4) Manufacturing & Sterilizing Process
- (5) Proposed label for Labisia Pumila in the United States
- (6) News article, research report for the product

Sincerely,

Annie Eng

H(312)280-1032 C(312)505-1318

E-mail:tradereng@hotmail.com

Suggested Use: take 2 capsules twice daily 1 hour before meal. The beneficial effects of supplements are build up gradually. Therefore it is recommended that this product is taken regularly to obtain continuous benefits.

Precautions: No serious side effects or drug interactions have been reported to date when used as directed. However, as with any supplement, consult a medical professional if you are taking a prescription medicine, are pregnant, or nursing a baby. In case of accidental ingestion/overdosage, seek the advise of a healthcare professional immediately. Keep out of reach of children.

Color variation is normal in this product No artificial colors, flavors, or preservatives Store in a cool dry place DO NOT USE IF EITHER SEAL IS BROKEN OR MISSING



270MG 60 CAPSULES

Labisia Pumila has been used for centuries by the local women in Southeast Asia for improving energy and overall women's vitality .Labisia Pumila may alleviate fatigue and soothes menopausal symptoms. Research shows that Labisia Pumila contains phytocestrogents that may enhance overall postpartum recovery. Labisia Pumila may help harmonize female reproductive system and menstrual cycle..

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Supplement Facts

Serving Size 2 Capsules Servings per Container 30

Amount Per Serving

Labisia Pumila Extract 540MG*

* Daily Value not established

Other Ingredients: Gelatin, Water

Distributed by Herbal Powers Inc Chicago, IL 60612 Product of Malaysia www..herbal-powers.com

labservice

(Company No: 119162-D)

LABSERVICE (M) SDIV BEID =

A1-23 & 24, PJ Industrial Park, Jalan Kemajuan, 46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia. Tel: 03-7576016/7576381/7567499 Fax: 603-7576488

LAB. N&S/13789/99/ms(A)
DATE 17th June 1999

CERTIFICATE OF ANALYSIS

ONE SAMPLE OF LABISIA PUMILA (KACIP FATIMAH) CAPSULES SUMMITTED BY M/S. TOMRICH MARKETING SDN.BHD., KUALA LUMPUR ON 7/6/99 AND MARKED:-

BRAND NAME: LAMILA 270MG MFG : 22.03.99 EXP : 21.03.2001

ÄNALYSIS	~		
		RESULTS	SPECIFICATIONS
STEROIDS			
Beclomethasone dipropionate		Negative	Negative
Betamethasone 17 - valerate	• • •	Negative	Negative
Cortisone acetate		Negative	Negative
Dexamethasone	• • •	Negative	Negative
Flumethasone		Negative	Negative
Hydrocortisone acetate	• • •	Negative	Negative
Prednisolone	• • •	Negative	Negative
Prednisone	• • •	Negative	Negative
MICROBIAL LIMIT TESTS			
Standard Plate Count per g			
0		3	4
@ 37 C for 48 hours		1.0x10	5x10 max
			2
Yeast & Moulds per g		Absent	5x10 max
E.coli per g (MPN)		Absent	Absent
Salmonella in 25 g		Absent	Absent
Pseudomonas aeruginosa per g		Ab sent	Absent
Staphylococcus aureus per g		Absent	Absent
Enterbacteria per g	•••	Absent	Absent
HEAVY METALS			
Arsenic (as As) , ppm		Not detected	1 5.0 max
Lead (as Pb) , ppm		0.95	10.0 max
Mercury (as Hg) , ppm		Not detected	

The above specifications was obtained from National Pharmaceutical Control Bureau (NPCB) for registration under Phase III of the implementation of the Control of Drugs and Cosmetics Regulations, 1984.

Labservice

LABSERVICE (M) SDN BHD

A1-23 & 24, PJ Industrial Park. Jalan Kemajuan, 46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia. Tel: 03-7576016/7576381/7567499

Fax : 603-7576488

DATE 17th June 1999

YOUR REF. :

OUR REF.:

LS/13789/99/ms(A)

MINERALS			
Calcium	(as Ca)	, ppm	 6731.65
Magnesium	(as Mg)	, ppm	 3398.62
Zinc	(as Zn)	, ppm	 18.20
Potassium	(as K)	, ppm	 44.20
Iron	(as Fe)	, ppm	 207.59

S. RTIOD Dis App Chair R Sc (Metb.)
Grad D.A.C.I., A.M.I.G., W.A.C.2.S.,
Discourse

CABSERVICE (M) SDN. BHD. (119182-0.)

LSL/ph

P.2/2

Tomrich Marketing Sdn Bhd

Product Names: Lamila (MAL19991267TC)

Active Ingredients: Labisia Pumila

Dosage: 270mg per capsule

MANUFACTURING & STERILIZING PROCESS

Stage 1: Preparation of raw materials

Stage 2: Encapsulating & Packing



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bahan pengawet, bahan tambahan, bahan

bengilangan produkini, tanpa dicampur

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kawasan hutan dan hanya akat dan

(tanpa memusnahkan habitat) dan

Asia Tenggara la diambil secara mapan

tumbuhan herba renik yang tumbuh secara semula jadi di dalam hutan hujan tropika di

Labisia Pumila (Kacip Fatima) ialah sejenis

MAKLUMAT PRODUK

EXPIRY DATE

ON HOTA8

MANUFACTURED DATE

250704 250704

шоэ цэн-цэрчимм 47000 Sungai Buloh Selangor D E Taman Industri S B Jaya, IT EYEL & S naist of on HEHBRICH FORESTS SDN BHD (129685-K) Distributed By

> MAL19991267TC WADE IN MALAYSIA

(Kacip Fatima)

Labisia Pumila

1028000

Labisia Pumila (Kacip Fallma) 100% 份加繫話 nour belote meet Companies (Mice daily 垂冊写卓60坪職藝・ DOSVCE 每有膠囊含有270mg Labisia Pumila itat this product is taken regularly to 量 合 diadually, it is therefore recommended 。用别错心 - 顶頭 effects of supplementation are built up 囊剔述2次每,次2日每 and women's health. The beneficial

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标本帶煙亞南東亚聂宇然自蘇 Labisia Pumila (Kacıp Fatıma) 慧



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Traditionally used for improving energy

NOITADION

without preservatives, additives, chemicals artificial flavours or colours.

are used in manufacturing the product,

harvested and only the roots and leaves

rainforests of S E Asia. It is sustainably

which grows naturally in the tropical small, slightly woody herbaceous plant

Labisia Pumila (Kacip Fatima) is a

РЯОРИСТ ІИГОЯМАТІОИ

BORANG 1 PERATURAN-PERATURAN KAWALAN DADAH DAN

[Peraturan 8(8)] PIHAK BERKUASA KAWALAN DADAH KEMENTERIAN KESIHATAN MALAYSIA

KOSMETIK 1984

PERAKUAN PENDAFTARAN

Nº 028045

PERAKUAN No:

MAL19991267TC

Nama dan alamat pemegang:

TOMRICH MARKETING SDN. BHD.

2, JALAN TIONG NAM 50350 KUALA LUMPUR.

BUTIR-BUTIR MENGENAI KELUARAN:

Nama

LAMILA CAPSULE

Nama Pengilang

YANLING NATURAL HYGIENE SDN. BHD.

Alamat Pengilang

1ST FLOOR, RESOURCE COMPLEX 33, JALAN SEGAMBUT ATAS

51200 KUALA LUMPUR.

No. Lesen Pengilang, (jika ada)

Keluaran di atas adalah didaftarkan tertakluk kepada syarat-syarat berikut :

SEMUA SYARAT PENDAFTARAN YANG DITETAPKAN OLEH PIHAK BERKUASA KAWALAN DADAH.

• •		/					
(Bersambung di atas kepingan lain yang	g dilampirkan kepada pera	ikuan ini *)					
Tempoh pendaftaran ini ialah dari	27/5/1999	19					
Tarikh	TO (DR) ABU BAKAR BIN D	erusi,					
Pihak Berkuasa Kawalan Dadah * Potong jika tidak pakai. Perakuan Dahulu No.							
Tarikh dikeluarkan	***************************************						



PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

PIHAK BERKUASA KAWALAN DADAH KEMENTERIAN KESIHATAN MALAYSIA



NAMA KELUARAN

LAMILA CAPSULE 270MG.

NO. PENDAFTARAN :

MAL19991267TC

INDIKASI YANG DILULUSKAN :

Traditionally used for improving energy and women's health.

CHE MOHD. ZIN THE AWANG

Setiausaha Pihak Berkuasa Kawalan Dadah Kementerian Kesihatan Malaysia

FORM 1

RULES OF DRUGS & COSMETICS-1984

(RULING 8(8))

DRUG CONTROL AUTHORITY MINISTRY OF HEALTH MALAYSIA

REGISTRATION

NO.: 028045

REGISTRATION NO: MAL19991267TC

Name and address of Holder:

TOMRICH MARKETING SDN BHD 2. JALAN TIONG NAM 50350 KUALA LUMPUR

PRODUCT DETAILS:

Name of Product : LAMILA CAPSULE

Name of Factory : YANLING NATURAL HYGIENE SDN BHD

Address of Factory: 1st FLOOR, RESOURCE COMPLEX

33, JALAN SEGAMBUT ATAS

51200 KUALA LUMPUR

Factory Licence No. (if available)

The above product follows all the stated conditions:

ALL CONDITIONS ARE SET BY THE DRUG CONTROL AUTHORITY

(continue on next page *)

Date of Registration is from : 27/5/1999

to: 27/5/2004

υō	Jε	е	:			

Tan Sri Dato (Dr.) ABU BAKAR
BIN DATO SULEIMAM
Chairman
DRUG CONTROL AUTHORITY

*Cut	here if	not in	use			
Previous	Registr	ation N	0,	• • • • • •		
Date Issu	ied		• • • • • •	• • • • • • •	• • • • • • •	

FORM 1

RULES OF DRUGS & COSMETICS-1984

DRUG CONTROL AUTHORITY MINISTRY OF HEALTH MALAYSIA

PRODUCT NAME : LAMILA CAPSULE 270MG

REGISTRATION NUMBER : MAL19991267TC

APPROVED INDICATION:

Traditionally used for improving energy and women's health.

CHE MOHD.ZIN CHE AWANG SECRETARY DRUG CONTROL AUTHORITY MINISTRY OF HEALTH MALAYSIA

"Senarai Keluaran Berdaftar / List of Registered Products Database" DRUG CONTROL AUTHORITY, MINISTRY OF HEALTH MALAYSIA

1 records matched your query: mal19991267tc (Search Criteria: Register Number)

Registration Number: MAL19991267TC

Product: LAMILA CAPSULE

Price: Not Available

Holder: TOMRICH MARKETING S/B **Address:** NO.2, JLN TIONG NAM,

Manufacturer: YANLING NATURAL HYGIENE S/B

Address: 16 & 18, JLN S.B. JAYA 11,

TAMAN INDUSTRI S.B.JAYA,

Ingredients: